PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	FOR FURTHER	SOS Form DCT/ICA/DOS
P780PC00	ACTION as we	see Form PCT/ISA/220 Il as, where applicable, item 5 below.
International application No.	International filing date (day/month/year)	(Earliest) Priority Date (day/month/year)
PCT/DK2004/000375	28/05/2004	30/05/2003
Applicant		
ALSENSA APS		
This International Search Report has b according to Article 18. A copy is being	een prepared by this International Searching Aut transmitted to the International Bureau.	hority and is transmitted to the applicant
This International Search Report consi	sts of a total of 9 sheets.	
X It is also accompanied	by a copy of each prior art document cited in this	report.
Basis of the report a. With regard to the language, the language in which it was filed, to	ne international search was carried out on the ba unless otherwise indicated under this item.	sis of the international application in the
The internation this Authority (al search was carried out on the basis of a transl Rule 23.1(b)).	ation of the international application furnished to
b. With regard to any nuc	leotide and/or amino acid sequence disclosed	in the international application, see Box No. !.
2. X Certain claims were fo	ound unsearchable (See Box II).	
3. X Unity of invention is la	acking (see Box III).	
4. With regard to the title ,		
	submitted by the applicant.	
	lished by this Authority to read as follows:	·
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		·
5. With regard to the abstract,		
	submitted by the applicant.	•
the text has been establi may, within one month fi	ished, according to Rule 38.2(b), by this Authority rom the date of mailing of this international searc	y as it appears in Box No. IV. The applicant h report, submit comments to this Authority.
6. With regards to the drawings,		
a. the figure of the drawings to be	published with the abstract is Figure No1_	·
X as suggested by		
as selected by the	nis Authority, because the applicant failed to sugg	est a figure.
	is Authority, because this figure better character	izes the invention.
b none of the figures is to b	pe published with the abstract.	
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INTERNATIONAL SEARCH REPORT

International application No.

PCT/DK2004/000375

Box No. IV Text of the abstract (Continuation of item 5 of the first sheet)

The present invention relates to a device (1) for delivering a medicament or a diagnostic agent to the skin or mucosa of an animal such as a human being, wherein a chamber (4) filled with the medicament or the diagnostic agent is separate from the housing (2) with a rod (29) capable of transferring the medicament or the diagnostic agent to the animal. The chamber (4) is connected to the housing (2) with the rod (29) before transfer of medicament or diagnostic agent. In particular the invention relates to a device (1) for delivering allergens in allergy tests.

Further documents are listed in the continuation of box C. Special categories of cited documents: A' document defining the general state of the art which is not considered to be of particular relevance E' earlier document but published on or after the international filing date C' document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) C' document referring to an oral disclosure, use, exhibition or other means	A. CLAS	SIFICATION OF SUBJECT MATTER					
Minimum documents are setzed office than minimum documentation to the extent that such documents are included in the fields searched Documentation searched office than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practical, search terms used) EPO—Internal C. DOCUMENTS CONSIDERED TO BE RELEVANT Category* Castino of document, with indication, where appropriate, of the relevant passages Relevant to claim No. DE 202 14 019 U (ROESCH AG MEDIZINTECHNIK) 16 January 2003 (2003-01-16) page 1, 11ne 12 — 11ne 21 page 9, 11ne 7 — 11ne 22 figure 1 Y Special categories of clied documents. A document defining the general state of the art which is not confidenced to set of periody, data and not in continual international filling data or pricely data and not in continual international filling data or pricely data and not in continual international filling data or pricely data and not in continual international filling data or pricely data and not in continual international filling data or pricely data and not in continual international filling data or pricely data and not in continual international filling data or pricely data and not in continual the application but or pricely data and not in continual international filling data or pricely data and not in continual international filling data or pricely data and not in continual the application but or pricely data and not in continual the application but or pricely data and not in continual the application or underlying the international search or pricely data and not in continual the application or underlying the international search or pricely data and not in continual the application or underlying the international search or pricely data and not in continual the application or underlying the international search or pricely data and not in continual the application or underlying the international search or pricely data and n	IPC 7	A61B5/103 A61B17/20 A61M37/00 A61M	15/50				
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& document member of the same patent family Date of the actual completion of the international search B December 2004 T7/12/2004 Authorized officer European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (-313-70) 340-2040 Tx 31 651 epo ni	*A* document defining the general state of the art which is not considered to be of particular relevance "E* earlier document but published on or after the international filing date "L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O' document referring to an oral disclosure, use, exhibition or other means "O' document published prior to the international filing date but "Y' document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such document is combined with one or more other such document is combination being obvious to a person skilled in the art.						
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FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 30,31

Claims 30,31:Rule 39.1(iv) PCT — Method for treatment of the human or animal body by therapy

International application No. PCT/DK2004/000375

INTERNATIONAL SEARCH REPORT

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)
This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:
1. X Claims Nos.: 30,31 because they relate to subject matter not required to be searched by this Authority, namely:
Claims 30,31:Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy
Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).
Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)
This International Searching Authority found multiple inventions in this international application, as follows:
see additional sheet
As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. X As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
Remark on Protest The additional search fees were accompanied by the applicant's protest.
No protest accompanied the payment of additional search fees.

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PATENT COOPERATION TREATY

INTERNATIONAL SEARCHING AUTHORITY To: WRITTEN OPINION OF THE see form PCT/ISA/220 INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1) Date of mailing (dayimonth/year) see form PCT/ISA/210 (second sheet) Applicant's or agent's file reference FOR FURTHER ACTION see form PCT/ISA/220 See paragraph 2 below International application No. International filing date (day/month/year) Priority date (day/month/year) PCT/DK2004/000375 28.05.2004 30.05.2003 International Patent Classification (IPC) or both national classification and IPC A61B5/103, A61B17/20, A61M37/00, A61M5/50 Applicant ALSENSA APS This opinion contains indications relating to the following items: ☑ Box No. I Basis of the opinion Box No. Ⅱ Priority ☑ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability Box No. IV Lack of unity of invention Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement ☐ Box No. VI Certain documents cited ☐ Box No. VII Certain defects in the international application Box No. VIII Certain observations on the international application 2. **FURTHER ACTION** If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1 bis(b) that written opinions of this International Searching Authority will not be so considered. If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later. For further options, see Form PCT/ISA/220. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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Fax: +31 70 340 - 3016

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Telephone No. +31 70 340-2978



20/558943

International application No. PCT/DK2004/000375

AP16 Rec'd PGT/FTO 3 0 NOV 2005

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	В	ox N	lo. I Basis of the opinion						
1.	 With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item. 								
		ıa	nis opinion has been established on the basis of a translation from the original language into the following nguage , which is the language of a translation furnished for the purposes of international search nder Rules 12.3 and 23.1(b)).						
2.	Wi ne	ith re	egard to any nucleotide and/or amino acid sequence disclosed in the international application and sary to the claimed invention, this opinion has been established on the basis of:						
	a. 1	type	of material:						
			a sequence listing						
			table(s) related to the sequence listing						
	b. f	form	at of material:						
			in written format						
			in computer readable form						
	c. t	ime	of filing/furnishing:						
	J		contained in the international application as filed.						
	i		filed together with the international application in computer readable form.						
	[furnished subsequently to this Authority for the purposes of search.						
3.		cop	addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto seen filed or furnished, the required statements that the information in the subsequent or additional pies is identical to that in the application as filed or does not go beyond the application as filed, as propriate, were furnished.						
4.	Add	litior	nal comments:						

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В	ox No. II	Priority
1. 🗵	The fo	ollowing document has not been furnished:
	X	copy of the earlier application whose priority has been claimed (Rule 43bis.1 and 66.7(a)).
		translation of the earlier application whose priority has been claimed (Rule 43bis.1 and 66.7(b)).
	Conse nevert	equently it has not been possible to consider the validity of the priority claim. This opinion has heless been established on the assumption that the relevant date is the claimed priority date.
2. 🗆	has be	pinion has been established as if no priority had been claimed due to the fact that the priority claim sen found invalid (Rules 43 <i>bis</i> .1 and 64.1). Thus for the purposes of this opinion, the international late indicated above is considered to be the relevant date.
3. 🗆	was no	not been possible to consider the validity of the priority claim because a copy of the priority document of available to the ISA at the time that the search was conducted (Rule 17.1). This opinion has heless been established on the assumption that the relevant date is the claimed priority date.
4. Ac	ditional	observations, if necessary:

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Bo ap	Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability								
Th ob	The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:								
	the entire international application,								
\boxtimes	claims Nos. 30,31								
bed	cause:								
	the said international application does not require an international	n, or al pre	the said claims Nos. relate to the following subject matter which eliminary examination (specify):						
. 🗆	the description, claims or drawi unclear that no meaningful opin	ngs nion ((indicate particular elements below) or said claims Nos. are so could be formed (specify):						
	the claims, or said claims Nos. could be formed.	are s	so inadequately supported by the description that no meaningful opinion						
\boxtimes	no international search report h	as b	een established for the whole application or for said claims Nos. 30,31						
	the nucleotide and/or amino aci C of the Administrative Instructi	d sec	quence listing does not comply with the standard provided for in Annex in that:						
	the written form		has not been furnished						
			does not comply with the standard						
	the computer readable form has not been furnished								
			does not comply with the standard						
	the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.								
	See separate sheet for further details								

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_	Bo	x No. IV	Lack of unity of i	nventio	on							
1	. 🗆	☐ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has:										
		☐ paid additional fees.										
			paid additional fees	under p	protest.							
			not paid additional for	ees.								
2.	×	This A	uthority found that the olicant to pay addition	e require al fees.	ement of u	nity of invention is no	t complied with an	d chośe not to invite				
3.	This	This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3										
		complied	d with									
	⊠ ı	not com	plied with for the follo	wing re	asons:							
		see se	parate sheet									
4.	Con	sequen	tly, this report has be	en esta	blished in I	respect of the followir	ng parts of the inte	rnational application:				
	□ all parts.											
	☑ the parts relating to claims Nos. 1-29,32,33,34,35,36											
		No. V ustrial a	Reasoned statements pplicability; citation	ent und	ler Rule 4: explanation	3 <i>bis</i> .1(a)(i) with rega	ard to novelty, inv	ventive step or				
1.	Stat	ement										
	Nov	elty (N)		Yes: No:	Claims Claims	3-29,33,35,36 1,2,32,34						
	inve	ntive ste	ep (IS)	Yes: No:	Claims Claims	1-29,32-36						
	indu	strial ap	plicability (IA)	Yes: No:	Claims Claims	1-29,32-36						
2.	Citat	ions and	d explanations									

see separate sheet

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (SEPARATE SHEET)

PCT/DK2004/000375

The following documents are referred to in this communication: 5 0 NOV 2005

- D1: DE 202 14 019 U (ROESCH AG MEDIZINTECHNIK) 16 January 2003 (2003-01-16)
- D2: WO 99/34739 A (MOELLSOEE CLAUS ;ROENBORG STEEN MEIER (DK)) 15 July 1999 (1999-07-15)
- D3: US-A-5 441 490 (SVEDMAN PAL) 15 August 1995 (1995-08-15)
- D4: DE 37 37 570 A (SBC SL) 3 November 1988 (1988-11-03)
 D1: EP-A-0 460 327 (MIYARISAN KABUSHIKI KAISHA) 11 December 1991 (1991-12-11)
- D5: EP-A-0 460 327 (MIYARISAN KABUSHIKI KAISHA) 11 December 1991 (1991-12-11)
- D6: US-A-5 104 375 (WOLF STEPHEN J ET AL) 14 April 1992 (1992-04-14)

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

No opinion has been established regarding claims 30 and 31 since their subject-matter refers to a method for treatment of the animal body by therapy, namely (see page 23, line 21,22) "delivering said medicament ... to said animal." Consequently, claims 30 and 31 concern a medical method which is excluded from international preliminary examination (Article 34(4)a, Rule 67(1)(iv) PCT).

Re Item IV

Lack of unity of invention

- 1 The application comprises two groups of claims:
- 1.1 Group I: Claims 1-26, 29, 32-34 are related to a delivery device comprising specific configurations of a rod and a chamber house having a chamber with first and second sealings and an axis intersecting both sealings (purpose: ease of use of a rod and secure storing of a medicament).
- 1.2 Group II: Claims 35, 36, 27, 28 are related to a device for delivering a medicament comprising labelling means (purpose: avoiding of multiple injection to the same animal).

The features common to claims 1 and 35 are disclosed in D1, see item V below. Consequently, these common features cannot constitute the special technical features referred to in Rule 13.2 PCT, second sentence.

Since in both independent claims of the above listed groups of claims no other common or corresponding technical features (the problems to be solved are different) exist, which can be considered as special technical features within Rule 13.2 PCT, second sentence, no technical relationship within the meaning of Rule 13.1 PCT between the different subjects as above can be seen.

Without a technical relationship the subjects are not so linked as to form a single inventive concept. As such the requirement of unity of invention according to Rule 13.1 PCT is not fulfilled.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1 First subject-matter: claims 1-26, 29, 32-34

1.1 INDEPENDENT CLAIM 1

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT. Document D1 discloses (see e.g. page 9, lines 7-22, Figure 1)

- a) a device for delivering a medicament or a diagnostic agent to the skin or mucosa of an animal, the device having
- b) at least one rod house (1) and at least one separate chamber house (2), wherein the chamber house (2) is capable of being connected to the rod house (1) (which is possible by the threads (15,16)),
- wherein the rod house (1) having at least one housing, the at least one housing having a distal end (the end including Gewinde (16)) and a proximal end, and at least one rod (5,7), the rod having a distal end (5) and at least one proximal end (7), and the rod being slidably arranged in the housing (1), the rod (5,7) being capable of being activated by being pushed towards the proximal end of the housing (1), and
- d) a chamber house (2) having a chamber (12), a first wall of the chamber (12) being

a first sealing (11) and a second wall of the chamber (12) being a second sealing (10), the first sealing (11) and the second sealing (10) being arranged so that an axis through the chamber (12) may intersect both sealings (10,11), and the chamber (12) having the medicament or the diagnostic agent.

- 1.2 Consequently, the present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Articla 33(2) PCT.
- 1.3 Dependent claims 2-26, 29 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step, see for example:
- 1.3.2 novelty

D1, page 9, lines 7-22, for claim 2;

1.3.3 inventive step

D2, see passages cited in the search report, for claims 4-9 and 13-20;

D5, see figure 1, for claim 21;

D6, see column 3, lines 48-50, figures 1 and 5, for claims 22-26;

Claim 8: D1 discloses "Auslöser 6" which, when in the position as represented in Figure 1, would clearly mark that the rod has been activated;

Claims 3,10-12 define features which present several straightforward possibilities from which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill.

Claim 29: The chamber disclosed in D1 is clearly intended to be filled with medicament or diagnostic agent.

2.1 INDEPENDENT CLAIM 32

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 32 is not new in the sense of Article 33(2) PCT. See document D1, page 9, lines 7-22, Figure 1 and the features as already listed in above paragraph 1.1 d).

Moreover, in addition to D1, also D2 and D3 (see passages referred to in the search report) present prior art documents which clearly disclose a chamber house such as defined in claim 32.

2.2 The subject-matter of dependent **claim 33** does not comply with the requirements of the PCT regarding inventive step since the chamber disclosed in D1 is not limited to a particular medicament and, consequently, could also be filled with an allergen or a combination of allergens which, as such, are already well known in the medical field.

3.1 INDEPENDENT CLAIM 34

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 34 is not new in the sense of Article 33(2) PCT. See document D1, page 9, lines 7-22, Figure 1 and the features as already listed in above paragraph 1.1 c).

- 4. Second subject-matter: claims 35,36,27,28
- 4.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of **claim 35** does not involve an inventive step in the sense of Article 33(3) PCT.

The delivery device as specified in claim 35 differs from the one as specified in claim 1 only in that the chamber house is provided with a labelling means.

The labelling means is also the only subject-matter not already anticipated by D1.

The problem to be solved by the present invention may therefore be regarded as avoiding of multiple injection to the same animal.

The solution proposed in claim 35 of the present application cannot be considered as involving an inventive step (Article 33(3) PCT) since such a labelling means is already described in document D4 (see column 1, lines 45-51, Figure 1) as providing the same advantages as in the present application. The skilled person would therefore regard it as a normal option to include this feature in the delivery device described in document D1 in order to solve the problem posed.

- 4.2 For the subject-matter of claim 36, see above paragraph 1.3.
- 4.3 Dependent claims 27, 28 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step, see for example: D4, column 1, lines 45-51, Figure 1.

Re Item VIII

Certain observations on the international application

- 1.1 The subject matter of Claim 34 does not fulfill the requirements of Article 6 PCT since it is not clear. In particular, it is not clear how a rod house can be connected to a chamber house according to claim 1 which comprises already a rod house. Consequently, claim 34 can only be related to claim 32 defining a chamber house.
- 1.2 The subject matter of Claim 32 does not fulfill the requirements of Article 6 PCT since it is not clear. In particular, it is not clear how a chamber house can be *made suitable* for being connected to a rod house according to claim 1 which comprises already a chamber house. Consequently, claim 32 can only be related to claim 34 defining a rod house.
- 2.1 Claims 6 is unclear, contrary to the requirements of Article 6 PCT, because of its inconsistent reference to "any of the preceding claims" although "the needle", as defined in it, can only be made dependent on claim 5.
- 2.2 Claims 9-12 can only be made dependent on claim 8 due to "marking means" as defined in this claim (Article 6 PCT).
- 2.3 Claim 14 can only be made dependent on claim 13 due "means for retracing the rod" (Article 6 PCT).
- 3 Claims 15 and 16: "the housing" should probably read "the rod housing".
- Figure 10 comprises surfaces with different shades of grey which does not comply with the requirements of Rule 11.13. PCT.